

REMARKS

Favorable consideration and allowance of the present application is respectfully requested.

Claims 1-5, 10-29, and 32, including independent claims 1, 19, and 24, are currently pending in the present application. Independent claim 1, for instance, is directed to a method for treating a wound by removing a protease from the site of the wound. The method comprises selecting fibers that are capable of removing a protease, wherein the fibers consist essentially of protein fibers. A wound dressing is formed from the fibers. The wound dressing and a protein selected from the group consisting of growth factors, cytokines, and chemokines are applied to the wound site so that the fibers are in contact with the wound site. At least a portion of the protease found at the wound site is allowed to be attracted to and entrapped by the fibers. The wound dressing is removed from the wound site so that at least a portion of the protease is removed from the wound site.

In the Final Office Action dated June 2, 2004, independent claims 1, 19, and 24 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,156,334 to Meyer-Ingold, et al. in view of WO 97/07273 to Ninagawa. Meyer-Ingold, et al. is directed to a wound covering for initiating or promoting healing of chronic wounds. Specifically, the wound covering is characterized in that substances which interact with interfering factors present in the wound exudates are covalently bonded to a carrier material. In the Final Office Action, the Examiner agreed that Meyer-Ingold, et al. fails to disclose a carrier material (wound dressing) consisting essentially of protein

fibers. Nevertheless, in the recent Advisory Action, it was asserted that Meyer-Ingold, et al. did disclose a protein-containing fibrous component consisting essentially of protein fibers.

In any event, Applicants respectfully submit that independent claims 1, 19, and 24, as presently amended, clearly define over Meyer-Ingold, et al. For instance, independent claim 1 now requires the formation of a wound dressing from "fibers that consist essentially of protein fibers." As is well known in the art, "protein fibers" include silk, wool, etc. In the context of the present claims, however, "protein fibers" do not include non-protein fibers (e.g., cotton or cotton-wool) that are only covalently attached to a protein molecule.

The recent Advisory Action cites dependent claim 17 as supporting the position that the fibers of Meyer-Ingold, et al. "consist essentially of protein fibers." Claim 17 requires that the protein (e.g., growth factor, cytokine, and/or chemokine) is included as part of the wound dressing itself. For example, growth factors may be attached to the protein fibers. Regardless of what molecules are attached to the fibers, however, the fibers themselves still consist essentially of protein fibers (e.g., silk, wool, etc.). This is simply not the case with Meyer-Ingold, et al. For instance, Examples 1-2 of Meyer-Ingold, et al. employ non-protein, cellulose fibers. Modification with a protein trapper molecule does not transform these cellulose fibers into protein fibers – i.e., they are still cellulose fibers. As an additional note, many of the embodiments of Meyer-Ingold, et al. do not even employ "fibers" to form the wound dressing. For example, gels and films are also utilized. (See e.g., Col. 8, ll. 42-44 and Examples 3-5). Accordingly, for at

least the reasons set forth above, Applicants respectfully submit that independent claims 1, 19, and 24 patentably define over Meyer-Ingold, et al.

The Final Office Action also cited Ninagawa in conjunction with Meyer-Ingold, et al. Specifically, the Final Office Action indicated that it would have been obvious to use the nonwoven fabric of Ninagawa as the carrier material simply because any known wound covering may be utilized in Meyer-Ingold, et al. However, Applicants note that the level of skill in the art cannot be relied upon to provide the suggestion to combine references. *M.P.E.P. § 2143.01*. Moreover, an allegation that modifications of the prior art would have been well within the ordinary skill of the art because all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *M.P.E.P. § 2143.01*. In the instant case, the Office Action has merely indicated that it is well known to use silk fabrics. Even if true, no objective motivation or suggestion would have been provided to utilize the particular nonwoven fabric of Ninagawa in Meyer-Ingold, et al. Instead, it appears that the rationale for the proposed combination is based only on the notion that it would have been "obvious to try", which is clearly improper under 35 U.S.C. §103(a). For instance, although cursorily mentioning a cotton-wool wound covering, the preferred carrier materials of Meyer-Ingold, et al. are said to include cellulose, alginates and other polysaccharides, and synthetic polymers. (Col. 8, ll. 27-44).

Applicants emphasize that neither of the cited references recognize the benefits obtained by the claimed invention. For instance, it is believed that proteases are able to

tunnel into the interior of the wound dressing because the protein fibers, or specific regions thereof, are substrates for the targeted protease. Hence, the protease may cut into the fiber, thereby moving away from the surface and effectively becoming removed from the equilibrium process at the fiber surface. In this manner, such deleterious proteases may be permanently and disproportionately removed from the wound site. Accordingly, for at least the reasons set forth above, Applicants respectfully submit that independent claims 1, 19, and 24 patentably define over the above-cited references.

In the Final Office Action, independent claims 1 and 24 were also rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,156,334 to Meyer-Ingold, et al. in view of U.S. Patent No. 5,447,505 to Valentine, et al. Specifically, the Office Action indicates that Valentine, et al. also discloses the use of wool, for instance, to treat wounds. However, Valentine, et al. fails to cure any of the defects discussed above. For at least this reason, Applicants respectfully submit that independent claims 1 and 24 patentably define over the above-cited references, taken singularly or in any proper combination. In addition, independent claims 1 and 19 were also rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Publication 2002/064551 to Edwards, et al. in view of Ninagawa and U.S. Patent No. 5,158,555 to Porzilli. However, Applicants previously submitted the declaration of Jason P. McDevitt, which established conception of the claimed invention prior to the earliest claimed priority date

of Edwards, et al. (February 29, 2000).¹ Thus, Edwards, et al. is not available as prior art to the present application and may not be used in the proposed § 103 rejection.

Applicants also respectfully submit that, at least for the reasons indicated above relating to the corresponding independent claims 1, 19, and 24, dependent claims 2-5, 10-18, 20-23, 25-29, and 32 patentably define over the references cited. However, Applicants also note that the patentability of such dependent claims does not necessarily hinge on the patentability of the respective independent claims. In particular, some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claims.

Thus, for at least the reasons set forth above, it is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Lewis is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

¹ Applicants' submission of this declaration is in no way an admission that Edwards, et al. either anticipates the claims of the present application under any applicable section of 35 U.S.C. § 102 or renders obvious, alone or in combination with other reference(s), the claims of the present application under 35 U.S.C. § 103.

Respectfully submitted,
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Date: 10/4/04